

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

U.S. Patent Number : 7,892,835 Issue Date: February 22, 2011
Application Number : 10/593,831 Confirmation No.: 3234
Applicant : Toshihiro AKAIKE, *et al.*
Filed : September 22, 2006
Title : PLURIPOTENT STEM CELL GROWING METHOD
TC/Art Unit : 1633
Examiner: : Scott LONG
Docket No. : 69719.000003
Customer No. : **21967**

MAIL STOP PATENT TERM EXT.

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR RECONSIDERATION OF
PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d)

Dear Sir:

Patentee submit a Request for Reconsideration of the Patent Term Adjustment under 37 C.F.R. § 1.705(d) of 481 days ("Request") indicated for the above-identified patent. It is respectfully requested that Patentee be granted a minimum patent term adjustment of 485 days.

U.S. Patent No. 7,892,835 ("the '835 patent") issued within two-months of the date of this Request. Accordingly, as required by 37 C.F.R. § 1.705(d), this request is timely.

In accordance with 37 C.F.R. § 1.705(b)(1), please charge the fee set forth in 37 C.F.R. § 1.18(e) (\$200) to the undersigned's **Deposit Account No. 50-0206**. In the event any additional fees are required for consideration of this request, the U.S. Patent and Trademark Office ("USPTO") is authorized to charge these fees to the undersigned's Deposit Account No. 50-0206.

Remarks begin on page 2.

REMARKS

Patentee requests reconsideration under 37 C.F.R. § 1.705(d) of the patent term adjustment for the '835 patent. In view of the following, it is respectfully requested that Patentee be granted a minimum patent term adjustment of at least 485 days.

Statement Under 37 C.F.R. § 1.705(b)(2)

The patent term adjustment ("PTA") under 35 U.S.C. § 154(b) listed on the face of the '835 patent is 481 days.¹ This determination is in error because the USPTO failed to take certain action within the time frame specified in 37 C.F.R. § 1.702(a) and failed to issue a patent within three years of the 371(b) date of the above-identified patent in accordance with 37 C.F.R. § 1.702(b).²

A. Calculation of PTA Under 37 C.F.R. § 1.703

The following facts are relevant for determining PTA for the '835 patent.

- March 23, 2004 — Priority document JP 2004-085393 is filed.³
- September 22, 2006 — U.S. Patent Application No. 10/593,831 is filed.⁴
- September 22, 2006 — 371(c) date assigned by USPTO to U.S. Patent Application No. 10/593,831.⁵
- September 23, 2006 — national stage commenced under 35 U.S.C. § 371(b) (*i.e.*, 30 months from the priority date).⁶
- November 22, 2007 — fourteen months from the 371(c) date of the application (*i.e.*, beginning of "A period").
- January 5, 2009 — mail date of Restriction Requirement (*i.e.*, end of "A period").⁷
- September 23, 2009 — three years from the 371(b) date of the application (*i.e.*, beginning of "B period").
- May 3, 2010 — Request for Continued Examination filed (*i.e.*, end of "B period").⁸

¹ See **Exhibit A** [first page of the '835 patent (*)].

² See also Notice Concerning Calculation of the Patent Term Adjustment under 35 U.S.C. § 154(b)(1)(B) involving International Applications Entering the National Stage Pursuant to 35 U.S.C. § 371 of September 9, 2009 (attached).

³ See **Exhibit A** [first page of the '835 patent at (30)].

⁴ See **Exhibit B** (Transmittal Sheet with USPTO date stamp).

⁵ See **Exhibit A** [first page of the '835 patent at (86)] and **Exhibit C** (USPTO Bibliographic Information).

⁶ See 35 U.S.C. § 371 and 37 C.F.R. § 1.702.

⁷ See **Exhibit D** (USPTO Transaction History).

1. "A" Periods Under 37 C.F.R. § 1.702(a)(2)

The number of days from the beginning of the "A period" (November 22, 2007, *i.e.*, fourteen months from the 371(c) date of the application) to the end of the "A period" (January 5, 2009, *i.e.*, the day a first office action was mailed) is 410 days. This is contrary to the USPTO's calculations.⁹

2. "B" Periods Under 37 C.F.R. § 1.702(b)

The number of days from the beginning of the "B period" (September 23, 2009, *i.e.*, three years from the 371(b) day of the application) to the end of the "B period" (May 3, 2010, *i.e.*, the day a Request for Continued Examination was filed) is 222 days. This is contrary to the USPTO's calculations.¹⁰

3. Delay Attributed to Applicant

The USPTO calculated Patentee's delay in the '835 patent as 147 days. This is in agreement with the USPTO's calculations.¹¹

4. PTA = (A Period + B Period) – Applicants Delay

The PTA should be calculated as follows:

A period = 410 days. *See* 1. above

B period = 222 days. *See* 2. above.

Applicants' delay = 147 days. *See* 3 above.

$(410 + 222) - 147 = 485$ days

Accordingly, Patentee respectfully request that the '835 patent be granted a minimum PTA of at least **485 days**.

⁸ *See Exhibit D* (USPTO Transaction History).

⁹ *See Exhibit E* (USPTO Patent Term Adjustment).

¹⁰ *See Exhibit D* (USPTO Transaction History).

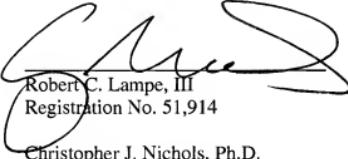
¹¹ *See Exhibit E* (USPTO Patent Term Adjustment).

CONCLUSION

In view of the above remarks, it is respectfully requested that this Request for Reconsideration of Patent Term Adjustment be favorably considered and that a corrected Determination of Patent Term Adjustment be issued to reflect a minimum patent term adjustment of at least 485 days.

Respectfully submitted,

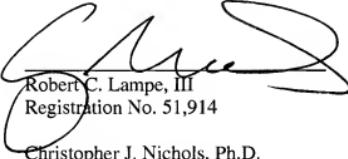
HUNTON & WILLIAMS LLP



Date: April 22, 2011

By:

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Exhibit A
U.S. Patent No. 7,892,835 (first page)



US007892835B2

(12) **United States Patent**
Akaike et al.

(10) **Patent No.:** **US 7,892,835 B2**
(45) **Date of Patent:** **Feb. 22, 2011**

(54) **PLURIPOTENT STEM CELL GROWING METHOD**

(75) Inventors: **Toshihiro Akaike**, Tokyo (JP); **Kelichi Fukuda**, Tokyo (JP); **Masato Nagaoaka**, Kanagawa (JP); **Uichi Koshihizumi**, Osaka (JP)

(73) Assignee: **Daiichi Sankyo Company, Limited**, Chuo-Ku, Tokyo (JP)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 481 days.

(21) Appl. No.: **10/593,831**

(22) PCT Filed: **Mar. 23, 2005**

(86) PCT No.: **PCT/JP2005/006006**

§ 371 (c)(1),
(2), (4) Date: **Sep. 22, 2006**

(87) PCT Pub. No.: **WO2005/090557**

PCT Pub. Date: **Sep. 29, 2005**

(65) **Prior Publication Data**

US 2007/0155013 A1 Jul. 5, 2007

(30) **Foreign Application Priority Data**

Mar. 23, 2004 (JP) 2004-085393

(51) **Int. Cl.**

C12N 15/09 (2006.01)
C12N 5/06 (2006.01)
C12N 5/08 (2006.01)

(52) **U.S. Cl.** 435/455; 435/354; 435/366

(58) **Field of Classification Search** None
See application file for complete search history.

(56) **References Cited**

FOREIGN PATENT DOCUMENTS

JP	2001061470 A	3/2001
WO	WO 01/51616	7/2001
WO	WO 01/66697 A2	9/2001
WO	WO 03/020920 A1	3/2003
WO	WO 03/087305	10/2003

OTHER PUBLICATIONS

Nagaoaka et al (Biotechnology Letters, 2002, 24: 1857-1862).
Nicolas et al (Ann. Microbiol. Paris, 126: 3-22, 1975).
Alonso et al (Int. J. Dev. Biol. 1991; 389-397).
Xu et al (Nature Biotechnology, Oct. 2001; 19: 971-974).
Song et al (PNAS, Nov. 12, 2002, 99(23): 14813-14818).
Fuchs et al (Cell, Mar. 19, 2004, 116: 769-778).
Hurt et al (Cancer Cell, Feb 2004; 5: 191-199).
Giebel et al (Mechanisms of Development, 1999; 83: 115-125).
Kovacs, et al., "Cadherin-Directed Actin Assembly: E-Cadherin Physically Associates with the Arp2/3 Complex to Direct Actin Assembly in Nascent Adhesive Contacts", Current Biology, vol. 12, p. 379-382, Mar. 5, 2002.

Nagaoaka, et al., "E-Cadherin-Coated Plates Maintain Pluripotent ES Cells without Colony Formation", PluS One, Issue 1, e15, p. 1-7, Dec. 2006.

Alonso, et al (1991) "The 19-LC cell line as a model for the analysis of differentiation", Int. J. Dev. Biol. 35: 389-397.

Andrews (2002) "From teratocarcinomas to embryonic stem cells" Phil. Trans. R Soc. Lond. 357: 405-417.

Artzi, et al. (1973) "Surface Antigens Common to Mouse Cleavage Embryos and Primitive Teratocarcinoma Cells in Culture" Proc. Nat. Acad. Sci. USA 70(10): 2988-2992.

ATCC Information on F9 Teratocarcinoma Cells (Catalog #) [downloaded from ATCC.org on Apr. 20, 2010].

Avner, et al. (1978) "The Genetics of Teratocarcinoma Transplantation: Tumor Formation in Allogeneic Hosts by the Embryonal Carcinoma Cell Lines F9 and PCC3." Immunogenetics 7: 103-115.

Nicolas, et al. (1975) Annales de Microbiologie 126(1): 3-22.

Painter (1928) "A Comparison of the Chromosomes of the Rat and Mouse with Reference to the Question of Chromosome Homology in Mammals." Genetics 13: 180-189.

M. Nagaoaka, et al., "Analysis of the E-cadherin function of Undifferentiated Cells by Immobilized E-cadherin Model Protein", Cell Structure and Function, vol. 28, No. 4, p. 327, IP-53, 2003.

M. Nagaoaka, et al., "E-cadherin/gf3 F9 Yugo Tanakushitsu Ni You Saibo Setchaku Kino No Seijo to Saisei Ikoaku Eno Oyo", Bio. Kobusai Symposium Koen Yoshihisa, vol. 13^W, pp. 31-32, 2003.

M. Nagaoaka, et al., "Saisei Iryo-Zairyo to Shite No E-cadherin Model Bunti No Soshiki Saikochiku Fao Oyo", The Japanese Society for Regenerative Medicine Zashi, vol. 1, No. 1, p. 83, Abstract No. 63, 2002.

M. Amit, et al., "Clonally Derived Human Embryonic Stem Cell Lines Maintain Pluripotency and Proliferative Potential for Prolonged Periods of Culture", Dev. Biol., vol. 227, No. 2, pp. 271-278, 2000.

M. Nagaoaka, et al., "Bio Material to Tissue Engineering Matrix Kogaku Ni Yoru Kansai No Bunka Zoshoku Seijo", Saisei Iryo, vol. 3, No. 2, pp. 47-54, (2005).

M. Nagaoaka, et al., "E-cadherin Model Tanakushitsu o Mochiita ES Saibo No Kokorutsu Baiyoho No Nakantu", Dai 27 Kai The Molecular Biology Society of Japan Nenka Program Koen Yoshihisa, p. 758, 2PB-224, Nov. 25, 2004.

* cited by examiner

Primary Examiner—Scott Long

(74) Attorney, Agent, or Firm—Hunton & Williams LLP

(57)

ABSTRACT

A novel growing method is provided for pluripotent stem cells such as ES cells. The method of the invention is a pluripotent stem cell growing method and gene transfer method in which pluripotent stem cells are cultured under conditions that maintain their undifferentiated state and pluripotency, the method being characterized by using a liquid medium and a culturing vessel having immobilized or coated on a substrate solid phase surface a molecule which is adhesive to the pluripotent stem cells in a fixed concentration, to grow the pluripotent stem cells in a dispersed state while maintaining their undifferentiated state and pluripotency, without using feeder cells, or to transfer and express a gene therein.

Exhibit B
Transmittal Sheet with USPTO date stamp

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER 58778.000007
INTERNATIONAL APPLICATION NO. PCT/JP2005/006006	INTERNATIONAL FILING DATE 23 March 2005	U.S. APPLICATION NO. (if known, see 37 CFR 1.51) 10/593831
		PRIORITY DATE CLAIMED 23 March 2004
TITLE OF INVENTION PLURIPOTENT STEM CELL GROWING METHOD		
APPLICANT(S) FOR DO/EO/US Toshihiro AKAIKE; Keiichi FUKUDA; Masato NAGAOKA and Uichi KOSHIMIZU		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
<p><input checked="" type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.</p> <p><input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.</p> <p><input type="checkbox"/> This express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</p> <p><input checked="" type="checkbox"/> The US has been elected (Article 31).</p> <p><input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) <ul style="list-style-type: none"> <input checked="" type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). <input type="checkbox"/> has been communicated by the International Bureau. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). </p> <p><input checked="" type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). <ul style="list-style-type: none"> <input checked="" type="checkbox"/> is attached hereto. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4). </p> <p><input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) <ul style="list-style-type: none"> <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). <input type="checkbox"/> have been communicated by the International Bureau. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. <input checked="" type="checkbox"/> have not been made and will not be made. </p> <p><input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p><input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</p> <p><input checked="" type="checkbox"/> An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</p>		
Items 11 to 20 below concern document(s) or information included:		
<p><input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</p> <p><input checked="" type="checkbox"/> An Assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</p> <p><input checked="" type="checkbox"/> A Preliminary Amendment.</p> <p><input checked="" type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.</p> <p><input checked="" type="checkbox"/> A power of attorney and/or change of address letter.</p> <p><input checked="" type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13^{ter}.2 and 37 CFR 1.821-1.825.</p> <p><input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).</p> <p><input checked="" type="checkbox"/> Other items or information:</p>		
International Search Report of PCT/JP2005/006006 (PCT/ISA/210); Notification of the Recording of a Change (Change of the Person) (Form PCT/IB/306); Notification of the Recording of a Change (Change of the Name of the 3 rd Assignee) (Form PCT/IB/306); PTO/SB/08 with 9 references; Submission of Sequence Listing with Paper Copy of Sequence Listing.		

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR 1.7)		INTERNATIONAL APPLICATION NO.		ATTORNEY'S DOCKET NUMBER	
10/593831		PCT/JP2005/006006		58778.000007	
<p>The following fees have been submitted:</p> <p><input checked="" type="checkbox"/> Basic National Fee (37 CFR 1.492(a)) \$ 300.00</p> <p><input checked="" type="checkbox"/> Examination Fee (37 CFR 1.492(c))</p>				CALCULATIONS PTO USE \$ 300.00	
If the written opinion prepared by ISA/US or the International Preliminary Examination Report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) \$ 0.00 All other situations \$ 200.00				\$ 200.00	
<input checked="" type="checkbox"/> Search Fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the International Preliminary Examination Report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) \$ 0.00 Search Fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority \$ 100.00 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB \$ 400.00 All other situations \$ 500.00				\$ 400.00	
TOTAL OF ABOVE CALCULATIONS = \$ 900.00				\$ 900.00	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing filed in an electronic medium) (37 CFR 1.492(j)). The fee is \$250.00 for each additional 50 sheets of paper or fraction					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)		RATE	
75 - 100	/50			x \$250.00	\$
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h))					
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	10 - 20 =		x	\$ 50.00	\$
Independent claims	2 - 3 =		x	\$200.00	\$
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+	\$360.00	\$ 360.00
TOTAL OF ABOVE CALCULATIONS =				\$ 1260.00	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees above are reduced by 1/2.					
SUBTOTAL = \$					
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)). \$ +					
TOTAL NATIONAL FEE = \$					
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property \$ +					
TOTAL FEES ENCLOSED = \$ 1300.00					

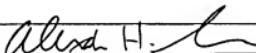
U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR 1.7)		INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
10/593831		PCT/JP2005/006006	5878.00000
<input checked="" type="checkbox"/> A check in the amount of <u>\$ 1300.00</u> to cover the above fees is enclosed. <input type="checkbox"/> Please charge Deposit Account No. <u>50-0206</u> in the amount of <u>\$</u> to cover the above fees. A duplicate copy of this sheet is enclosed. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>50-0206</u> A duplicate copy of this sheet is enclosed. <input type="checkbox"/> Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.			
NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.			
SEND ALL CORRESPONDENCE TO: CUSTOMER NO. 21967 Intellectual Property Department Hunton & Williams LLP 1900 K Street, N.W.; Suite 1200 Washington, DC 20006-1109 (202) 955-1500 (telephone) (202) 778-2201 (facsimile)			
 SIGNATURE Robert M. Schulman; Alexander H. Spiegler		NAME 31,196, 56,625	
REGISTRATION NUMBER 31,196, 56,625		DATE September 22, 2006	

Exhibit C
USPTO Bibliographic Information

10/593,831 PLURIPOTENT STEM CELL GROWING METHOD

04-22-
2011:09:44:51**Bibliographic Data**

Application Number:	10/593,831	Customer Number:	21967
Filing or 371 (c) Date:	09-22-2006	Status:	Patented Case
Application Type:	Utility	Status Date:	02-02-2011
Examiner Name:	LONG, SCOTT	Location:	ELECTRONIC
Group Art Unit:	1633	Location Date:	-
Confirmation Number:	3234	Earliest Publication No:	US 2007-0155013 A1
Attorney Docket Number:	69719.000003	Earliest Publication Date:	07-05-2007
Class / Subclass:	435/455	Patent Number:	7,892,835
First Named Inventor:	Toshihiro Akaike , Tokyo, (JP)	Issue Date of Patent:	02-22-2011

Title of Invention: PLURIPOTENT STEM CELL GROWING METHOD

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Exhibit D
USPTO Transaction History

10/593,831	PLURIPOTENT STEM CELL GROWING METHOD	04-22-2011::09:36:54
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Transaction History

Date	Transaction Description
03-10-2011	Sequence Moved to Public Database
02-22-2011	Recordation of Patent Grant Mailed
02-02-2011	Issue Notification Mailed
02-22-2011	Patent Issue Date Used in PTA Calculation
01-18-2011	Dispatch to FDC
01-14-2011	Application Is Considered Ready for Issue
01-13-2011	Issue Fee Payment Verified
01-13-2011	Issue Fee Payment Received
11-09-2010	Sequence Forwarded to Pubs on Tape
10-20-2010	Mail Examiner Interview Summary (PTOL - 413)
10-20-2010	Mail Examiner's Amendment
10-20-2010	Mail Notice of Allowance
10-15-2010	Document Verification
10-15-2010	Notice of Allowance Data Verification Completed
10-15-2010	Case Docketed to Examiner in GAU
10-15-2010	Examiner's Amendment Communication
09-29-2010	Examiner Interview Summary Record (PTOL - 413)
09-23-2010	Date Forwarded to Examiner
09-21-2010	Response after Non-Final Action
09-21-2010	Request for Extension of Time - Granted
08-18-2010	Mail Examiner Interview Summary (PTOL - 413)
08-16-2010	Examiner Interview Summary Record (PTOL - 413)
05-27-2010	Mail Non-Final Rejection
05-27-2010	Mail Examiner Interview Summary (PTOL - 413)
05-27-2010	Non-Final Rejection
05-03-2010	Information Disclosure Statement considered
05-24-2010	Examiner Interview Summary Record (PTOL - 413)
05-03-2010	Information Disclosure Statement (IDS) Filed
05-03-2010	Information Disclosure Statement (IDS) Filed
05-05-2010	Date Forwarded to Examiner
05-03-2010	Request for Continued Examination (RCE)
05-05-2010	Disposal for a RCE / CPA / R129
05-03-2010	Request for Extension of Time - Granted
05-03-2010	Workflow - Request for RCE - Begin
11-02-2009	Mail Final Rejection (PTOL - 326)
10-28-2009	Final Rejection
09-13-2009	Date Forwarded to Examiner
07-20-2009	Response after Non-Final Action
07-20-2009	Request for Extension of Time - Granted
03-18-2009	Mail Non-Final Rejection
03-16-2009	Non-Final Rejection
10-01-2007	Information Disclosure Statement considered

09-22-2006 Information Disclosure Statement considered
02-04-2009 Date Forwarded to Examiner
02-02-2009 Response to Election / Restriction Filed
01-05-2009 Mail Restriction Requirement
01-02-2009 Restriction/Election Requirement
10-01-2007 Information Disclosure Statement (IDS) Filed
10-09-2007 Case Docketed to Examiner in GAU
10-01-2007 Information Disclosure Statement (IDS) Filed
07-05-2007 PG-Pub Issue Notification
09-22-2006 Information Disclosure Statement (IDS) Filed
04-23-2007 Application Dispatched from OIPE
09-23-2006 371 Completion Date
03-26-2007 Sent to Classification Contractor
03-26-2007 Notice of DO/EO Acceptance Mailed
10-21-2006 Cleared by OIPE CSR
10-10-2006 CRF Is Good Technically / Entered into Database
09-22-2006 CRF Disk Has Been Received by Preexam / Group / PCT -
09-22-2006 Initial Exam Team nn

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Exhibit E
USPTO Patent Term Adjustment

10/593,831	PLURIPOTENT STEM CELL GROWING METHOD	04-22-2011:09:37:23
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Patent Term Adjustments

Patent Term Adjustment (PTA) for Application Number: 10/593,831

Filing or 371(c) Date:	09-22-2006	Overlapping Days Between {A and B} or {A and C}:	0
Issue Date of Patent:	02-22-2011	Non-Overlapping USPTO Delays:	628
A Delays:	409	PTO Manual Adjustments:	0
B Delays:	219	Applicant Delays:	147
C Delays:	0	Total PTA Adjustments:	481

Patent Term Adjustment History Explanation Of Calculations

Number	Date	Contents Description	PTO (Days)	APPL (Days)	Start
66.5	05-02-2010	PTA 36 Months	219		66.4
66.4	09-25-2006	Commencement Date			0
66	02-22-2011	Patent Issue Date Used in PTA Calculation			0
65	01-19-2011	Export to Final Data Capture			0
64	01-18-2011	Dispatch to FDC			0
63	01-14-2011	Application Is Considered Ready for Issue			0
62	01-13-2011	Issue Fee Payment Verified			0
61	01-13-2011	Issue Fee Payment Received			0
60	12-21-2010	Finished Initial Data Capture			0
59	11-09-2010	Sequence Forwarded to Pubs on Tape			0
58	10-25-2010	Export to Initial Data Capture			0
55	10-20-2010	Mail Notice of Allowance			0
54	10-15-2010	Document Verification			0
53	10-15-2010	Issue Revision Completed			0
52	10-15-2010	Notice of Allowance Data Verification Completed			0
51	10-15-2010	Case Docketed to Examiner in GAU			0
48	10-15-2010	Examiner's Amendment Communication			0
47	09-29-2010	Examiner Interview Summary Record (PTOL - 413)			0

46	10-13-2010	Allowability Notice	0
45	09-23-2010	Date Forwarded to Examiner	0
44	09-21-2010	Response after Non-Final Action	25 40
43	09-21-2010	Request for Extension of Time - Granted	0
42	08-18-2010	Mail Examiner Interview Summary (PTOL - 413)	0
41	08-16-2010	Examiner Interview Summary Record (PTOL - 413)	0
40	05-27-2010	Mail Non-Final Rejection	0
39	05-27-2010	Mail Examiner Interview Summary (PTOL - 413)	0
38	05-27-2010	Non-Final Rejection	0
37	05-03-2010	Information Disclosure Statement considered	0
35	05-24-2010	Examiner Interview Summary Record (PTOL - 413)	0
34	05-03-2010	Information Disclosure Statement (IDS) Filed	0
33	05-03-2010	Information Disclosure Statement (IDS) Filed	0
32	05-05-2010	Date Forwarded to Examiner	0
31	05-03-2010	Amendment Submitted/Entered with Filing of CPA/RCE	0
30	05-03-2010	Request for Continued Examination (RCE)	90 26
29	05-05-2010	Disposal for a RCE / CPA / R129	0
28	05-03-2010	Request for Extension of Time - Granted	0
27	05-03-2010	Workflow - Request for RCE - Begin	0
26	11-02-2009	Mail Final Rejection (PTOL - 326)	0
25	10-28-2009	Final Rejection	0
24	09-13-2009	Date Forwarded to Examiner	0
23	07-20-2009	Response after Non-Final Action	32 21
22	07-20-2009	Request for Extension of Time - Granted	0
21	03-18-2009	Mail Non-Final Rejection	0

20	03-16-2009	Non-Final Rejection	0
19	10-01-2007	Information Disclosure Statement considered	0
17	02-04-2009	Date Forwarded to Examiner	0
16	02-02-2009	Response to Election / Restriction Filed	0
15	01-05-2009	Mail Restriction Requirement	409
14	01-02-2009	Restriction/Election Requirement	0
13	10-01-2007	Information Disclosure Statement (IDS) Filed	0
12	10-09-2007	Case Docketed to Examiner in GAU	0
11	10-01-2007	Information Disclosure Statement (IDS) Filed	0
10	07-05-2007	PG-Pub Issue Notification	0
8	04-23-2007	Application Dispatched from OIPE	0
7	09-23-2006	371 Completion Date	0
6	03-26-2007	Sent to Classification Contractor	0
5	03-26-2007	Notice of DO/EO Acceptance Mailed	0
4	10-21-2006	Cleared by OIPE CSR	0
3	10-10-2006	CRF Is Good Technically / Entered into Database	0
0.5	03-23-2005	International Filing date	0

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**Notice Concerning Calculation of the Patent Term Adjustment under 35 U.S.C.
§ 154(b)(1)(B) involving International Applications Entering the National Stage
Pursuant to 35 U.S.C. § 371**

Summary: The computer program that the United States Patent and Trademark Office (USPTO) uses to calculate patent term adjustment incorrectly calculates the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B) in international applications if the requirements of 35 U.S.C. § 371 are not fulfilled on the date that the national stage commenced under 35 U.S.C. § 371(b) or (f). The USPTO is in the process of correcting this computer program. Applicants seeking a revised patent term adjustment determination based on this calculation must submit a timely request for reconsideration of the patent term adjustment indicated in the patent under 37 CFR 1.705(d).

Background: Under 35 U.S.C. § 154(b)(1)(B), an applicant is entitled to additional patent term adjustment if the issue of an original patent is delayed due to the failure of the USPTO to issue a patent within three years after the actual filing date of the application. The USPTO implemented the three-year pendency provision in 35 U.S.C. § 154(b)(1)(B) in 37 CFR 1.702(b) and 37 CFR 1.703(b). See Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 Fed. Reg. 56365, 56391-92 (Sept. 18, 2000) (final rule). The USPTO indicated the three-year pendency provision in 35 U.S.C. § 154(b)(1)(B) is measured from the date that the national stage commences under 35 U.S.C. § 371(b) or (f) in an international application. See Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 Fed. Reg. at 56382-84.

The USPTO makes patent term adjustment determinations by a computer program that uses the information recorded in the USPTO's automated patent application information system (the Patent Application Locating and Monitoring system or PALM system), except when an applicant requests reconsideration pursuant to 37 CFR 1.705. See Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 Fed. Reg. at 56370, 56380-81.

Discussion: The USPTO is in the process of correcting an error in the computer program that it uses to calculate the patent term adjustment that affects patents issuing from international applications entering the national stage as to the United States pursuant to 35 U.S.C. § 371. The USPTO's computer program incorrectly calculates the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B) in international applications as being measured from the date that the requirements of 35 U.S.C. § 371 were fulfilled rather than the date the national stage commenced under 35 U.S.C. § 371(b) or (f) in the international application. The USPTO is correcting the computer program to reflect that the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B) in international applications is measured from the date the national stage commenced under 35 U.S.C. § 371(b) or (f) in the international application.

An applicant seeking a revised patent term adjustment determination based upon the three-year pendency provision must submit a timely request for reconsideration of the patent term adjustment indicated in the patent. The USPTO does not calculate and inform the applicant of the patent term adjustment based upon the three-year pendency

provision of 35 U.S.C. § 154(b)(1)(B) in the notice of allowance because the USPTO must know the date the patent will issue to be able to calculate the patent term adjustment based upon this provision. Thus, reconsideration of the patent term adjustment indicated in the patent as it relates to the three-year pendency provision of 35 U.S.C.

§ 154(b)(1)(B) is **not** considered a matter that could have been raised in an application for patent term adjustment under 37 CFR 1.705(b) (provides for reconsideration of the patent term adjustment indicated in the notice of allowance). Therefore, a request for reconsideration of the patent term adjustment calculation based on the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B) will be considered timely under 37 CFR 1.705(d) if filed within two months of the date the patent issued.

For Further Information Contact: The Office of Patent Legal Administration by telephone at (571) 272-7702, or by mail addressed to: Mail Stop Comments-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: 9/9/09

David J. Kappos

Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office